

In the United States Court of Federal Claims

No. 17-838

Filed: March 9, 2023[†]

JUDY ECHOLS,

Petitioner,

v.

**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Respondent.

Jennifer Anne Gore Maglio, Maglio Christopher and Toale, PA, Sarasota, FL, for Petitioner.

Katherine C. Esposito, Trial Attorney, *Gabrielle M. Fielding*, Assistant Director, *Heather Pearlman*, Deputy Director, *C. Salvatore D'Alessio*, Acting Director, and *Brian M. Boynton*, Principal Deputy Assistant Attorney General, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent.

MEMORANDUM OPINION AND ORDER

TAPP, Judge.

The Court has long recognized that review of vaccine claims entails a foray into “a field bereft of complete and direct proof of how vaccines affect the human body[]” *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378, 1379 (Fed. Cir. 2009). To reconcile this reality with the National Vaccine Injury Compensation Program’s, 42 U.S.C. §§ 300aa-10 *et seq.* (2012) (“Vaccine Act”), goal—which is to award vaccine-injured persons with generosity—the Vaccine Act empowers the special masters who adjudicate vaccine claims to exercise broad discretion in evaluating the merits of those claims. As such, the evidence heard by the special master should be the “main event” rather than a mere “tryout[;]” the deference afforded to factual findings

[†] This Order was originally filed under seal on November 30, 2022, (ECF No. 100). The Court provided parties the opportunity to review this opinion for any proprietary, confidential, or other protected information and submit proposed redactions no later than December 14, 2022. On December 14, 2022, the parties filed a Joint Status Report wherein neither party requested redactions, (ECF No. 103). Thus, the sealed and public versions of this Order are identical, except for the publication date and this footnote.

require that the decision of the Special Master be affirmed here. *Anderson v. City of Bessemer City, NC*, 470 U.S. 564, 575 (1985) (quoting *Wainwright v. Sykes*, 433 U.S. 72, 90 (1977)).¹

Judy Echols (“Ms. Echols”), petitioned for compensation pursuant to the Vaccine Act, alleging that she suffered complications after administration of the influenza (“flu”) vaccine. (Compl., ECF No. 1). Specifically, Ms. Echols alleged she experienced numbness, decreased sensation, muscle wasting, and the inability to use her left arm. (*Id.* at 2). The Special Master reviewed Ms. Echols’s claim, ultimately concluding that Ms. Echols “carried her burden to establish causation-in-fact” and therefore, was “entitled to compensation for neuralgic amyotrophy[.]” *Echols v. Sec’y of Health & Hum. Servs.*, No. 17-838V, 2021 WL 4891589, at *1, *26 (Fed. Cl. Spec. Mstr. Sept. 14, 2021), (Ruling on Entitlement, ECF No. 71). Consequently, on June 6, 2022, the Special Master awarded Ms. Echols approximately \$110,000 for past pain and suffering and unreimbursed expenses. *Echols v. Sec’y of Health & Hum. Servs.*, No. 17-838V, 2022 WL 2301611 (Fed. Cl. Spec. Mstr. June 6, 2022) at *1, (Decision, ECF No. 89).

The Secretary of Health and Human Services (“Secretary”) seeks review, (ECF No. 91), arguing that the Special Master’s legal conclusions and attendant factual findings should be set aside as arbitrary, capricious, an abuse of discretion, or otherwise contrary to law. (Memo. Mot. for Rev. (“Resp’t’s Mot.”) at 5, ECF No. 92). As explained below, the Court denies the Secretary’s Motion for Review and affirms the Special Master’s ruling.

I. Background

The relevant facts are those primarily detailed by and determined to be “consistent and not disputed” by the Special Master. *See Echols*, 2021 WL 4891589, at *6–13. On October 28, 2015,² Ms. Echols first reported left shoulder pain unrelated to a specific injury to her orthopedist. *Id.* at *7. Her orthopedist noted, “[o]n the internal rotation view, no pathological lesion, no fractures and no major degenerative changes[;];” she was diagnosed with left shoulder impingement and bursitis.³ *Id.* (citing Pet. Ex. 11 at 15).⁴ On November 5, Ms. Echols complained of left shoulder pain, starting five weeks prior, to her primary care provider. *Id.* at *8. Specifically, she described the pain as a persistent sharp stabbing that was gradually

¹ Although *Anderson* reviews factual findings under Federal Rules of Civil Procedure Rule 52(a) and the review of a special master’s findings involve a different standard, *see* 42 U.S.C. § 300aa-12(e)(2)(B), the logical underpinnings are the same.

² All dates occurred in 2015 unless otherwise specified.

³ “Bursitis is a swelling or inflammation of a bursa, which is a synovium-lined, sac-like structure found throughout the body near bony prominences and between bones, muscles, tendons, and ligaments.” *Echols*, 2021 WL 4891589, at *14 (citing Williams et al., Bursitis, StatPearls – NCBI Bookshelf (National Library of Medicine, National Institutes of Health), *available at* <https://www.ncbi.nlm.nih.gov/books/NBK513340/>).

⁴ Ms. Echols submitted Pet. Exs. 1–12 via compact disc on June 26, 2017. The submission does not have an ECF No.

worsening, particularly when engaging in physical activity like sports, work duties, overhead activities, lifting, or throwing. *Id.* Notably, Ms. Echols retained “good mobility” and did not report loss of sensation or strength in her arm. *Id.* (citing Pet. Ex. 11 at 40–41).

On November 12, Ms. Echols was administered the flu vaccine. *Id.* at *8. During this visit, her pulmonologist recorded that Ms. Echols “denie[d] tingling or numbness [or] muscular weakness[]” and her neurological exam revealed “no muscle weakness, no sensory loss.” *Id.* (citing Pet. Ex. 11 at 101). Approximately four hours after the administration of the vaccine, Ms. Echols presented at the Northeast Alabama Regional Medical Center (“NEARC”) emergency department (“ED”) complaining of left shoulder numbness, tingling, weakness, and difficulty moving her arm. *Id.* At the hospital, a nurse practitioner made conflicting notes about the onset of these symptoms. She wrote “left arm weakness since [November 6]” and “symptoms have been occurring for four days,” which would change the onset to November 8. *Id.* (citing Pet. Ex. 5 at 249). Then a registered nurse conducted an assessment and noted that Ms. Echols’s “numb arms” and “weakness” began that day, “Thursday, November 12, 2015.” *Id.* The basis of these disparate dates is unknown and was not elaborated upon in the Special Master’s opinion.

On November 16, Ms. Echols’s orthopedist recorded that she could not move her left arm and that she “woke up last Thursday morning with numbness and unable to use the left arm.” *Id.* at *9 (citing Pet. Ex. 11 at 9). Ms. Echols saw a neurologist on November 19, who recorded a seven-day history of left arm paralysis and numbness dating their onset to November 12. *Id.* Subsequently, Ms. Echols underwent a series of tests and attended appointments for left arm paralysis. *Id.* During an appointment, Ms. Echols’s neurologist diagnosed her with “left brachial plexopathy possibly due to the flu vaccine.” *Id.* (citing Pet. Ex. 2 at 25). Ms. Echols’s physical therapist also wrote on an intake form that her symptoms began four months prior following a flu shot. *Id.* (citing Pet. Ex. 5 at 120). Again, the inconsistent reporting or recording regarding onset is unexplained.

Ms. Echols petitioned for vaccine compensation on June 21, 2017, claiming that the flu vaccine caused her left arm weakness, numbness, and paralysis and that she was entitled to compensation under the Vaccine Act. (*See generally* Compl.). Under the Vaccine Act, petitioners may demonstrate eligibility for an award through two methods: (1) an injury listed on the Vaccine Injury Table occurred within the requisite period, or (2) an unlisted injury was caused-in-fact by a vaccine listed on the Table. 42 C.F.R. § 100.3; 42 U.S.C. § 300aa-11(c)(1)(C). Here, the Special Master’s underlying decision was predicated on whether Ms. Echols provided sufficient evidence to show the flu vaccine factually caused her symptoms. To establish actual causation, Ms. Echols was required to “show by preponderant evidence” (1) a medical theory connecting the vaccination and injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The Special Master’s finding that the flu vaccine caused Ms. Echols’s neuralgic amyotrophy chiefly relied on a review of scientific literature on the condition and expert testimony. *See Echols*, 2021 WL 4891589, at *16–26. Ms. Echols’s expert, Dr. Daniel DiCapua

(“Dr. DiCapua”),⁵ and the Secretary’s experts, Dr. Brian Callaghan (“Dr. Callaghan”)⁶ and Dr. S. Mark Tompkins (“Dr. Tompkins”),⁷ all discussed the work of van Alfen, a “recognized authority” on neuralgic amyotrophy. *See Echols*, 2021 WL 4891589, at *16–26. In sum, van Alfen wrote the “classic form” of the condition typically starts with “new-onset pain in the shoulder or upper arm” that “generally becomes unbearable . . . within a few hours.” *Id.* at *15 (citing Pet. Ex. 15.4 at 1, ECF No. 38-5). The severe pain lasts for an average of 27.5 days. *Id.* at *16 (citing Resp’t Ex. A1 at 4, ECF No. 40-2). However, females experience shorter periods of pain, averaging 23.3 days, to males’ 45.3 days. *Id.* Notably, only 10% of neuralgic amyotrophy patients reported their initial pain lasting more than sixty days. *Id.* Regarding the onset of symptoms, van Alfen also reported that “[i]n the attacks characterized by initial pain, the first signs of weakness appeared within [twenty-four] hours in 33.5% of the patients, after [one to seven] days in 39.3%, and [one to two] weeks in 14.1%. In 27.2% of all cases, [weakness] did not manifest itself until [over two] weeks later.” *Id.* (citing Resp’t Ex. A1 at 5).

In light of van Alfen’s reports, Dr. DiCapua testified that Ms. Echols’s symptoms prior to vaccination—namely “shoulder pain coupled with normal active and passive ranges of motion”—would be “exceedingly unlikely” if she was experiencing neuralgic amyotrophy. *Id.* at *16. He emphasized that in van Alfen’s case series, 80% of males and 97.4% of females with neuralgic amyotrophy experienced increased mechanical sensitivity.⁸ *Id.* (citing Pet. Ex. 17 at 2, ECF No. 60-2). Conversely, Dr. Callaghan testified that although most neuralgic amyotrophy patients experienced mechanical sensitivity, Ms. Echols’s medical records before and after her vaccination do not explicitly address such sensitivity. *Id.* at *17 (citing Pet. Ex. 2 at 4, 7, 10, 13 (primary care records); Pet. Ex. 3 at 10, 19, 27, 41(orthopedic records)). Regarding Ms. Echols’s left arm weakness, Dr. Callaghan stated that weakness is often not detected by non-neurologists and that could have occurred here. *Id.* at *18 (citing Resp’t Ex. E at 2, ECF No. 54-2; Resp’t Ex. G at 2, ECF No. 61-1).⁹ Drawing on this testimony and the scientific literature, the Special Master concluded that four hours after her vaccination, Ms. Echols experienced symptoms of weakness, numbness, and tingling in her left arm and hand that were new. *Id.* at *18.

The Special Master determined that Ms. Echols satisfied *Althen* prong one, requiring a “reputable” scientific or medical theory based on “sound and reliable medical or scientific explanation.” *Id.* at *6, 18–20 (citing *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994)). To do so, the Special Master reviewed Dr. DiCapua’s testimony that

⁵ Admitted as expert in the subjects of neurology, neuromuscular disorders, and peripheral neuropathy. *Echols*, 2021 WL 4891589, at *2, n.5.

⁶ Admitted as an expert in the subjects of neurology, neuromuscular disorders, and peripheral neuropathy. *Echols*, 2021 WL 4891589, at *2, n.6.

⁷ Admitted as an expert in the subject of immunology. *Echols*, 2021 WL 4891589, at *2, n.7.

⁸ Defined as “[p]ain elicited by movement of or pressure on the affected limb[.]” *Echols*, 2021 WL 4891589, at *15.

⁹ The Special Master noted testimony “would be contrary to [his] bench ruling finding of fact.” *Echols*, 2021 WL 4891589, at *18.

neuralgic amyotrophy is “most likely autoimmune and can be precipitated by infections and vaccines, including inactivated flu vaccine[,]” and determined this theory was supported by the literature. *Id.* at *18 (citing Pet. Ex. 15 at 3, ECF No. 38). Specifically, the Special Master cited two reports, including a van Alfen case study that found “43.5% of subjects had antecedent infections and 4.3% had antecedent vaccines[,]” accompanied by at least three reported flu vaccines that preceded neuralgic amyotrophy. *Id.* (citing Resp’t Ex. A1 at 6; Pet. Ex. 15.8 at 1–2, ECF No. 38-9). The Special Master also reviewed Dr. Callaghan and Dr. Tompkins’s testimony that the scientific literature, including van Alfen studies, did not support causation. *See id.* at *21–22. Dr. Tompkins testified that “associations in case reports” fail to “provide evidence of causation.” (Resp’t Ex. C at 2, ECF No. 41-1). Dr. Callaghan similarly provided that the case studies “only support a proximal temporal relationship” and “a proximate temporal relationship alone is insufficient to prove causation.” (Resp’t Ex. A at 2, ECF No. 40-1). However, the Special Master concluded that the van Alfen studies were “the most persuasive explanation of neuralgic amyotrophy” and as such, *Althen* prong one was adequately established. *Echols*, 2021 WL 4891589, at *22–23.

Furthermore, the Special Master found Ms. Echols proved a “logical sequence of cause and effect showing that the vaccination was the reason for [her] injury[,]” thereby establishing *Althen* prong two. *Id.* at *5, 24–26 (citing *Althen*, 418 F.3d at 1278). Relying on Ms. Echols’s medical records, van Alfen literature, and Dr. DiCapua’s testimony, the Special Master determined that Ms. Echols’s vaccination caused the onset of her neuralgic amyotrophy. *Id.* Specifically, the Special Master differentiated her bursitis, which was “associated with some degree of inflammation which loosened the blood nerve barrier,” from the neuralgic amyotrophy that was “trigger[ed]” by the flu vaccine. *Id.* at *26. When reviewing Ms. Echols’s medical records, the Special Master refused to assume that notes (months after vaccination) associating the flu vaccine with the neuralgic amyotrophy were the product of Ms. Echols’s own “reported belief.” *Id.* at *24. Instead, he determined these later records offered a small degree of probative evidence supporting Ms. Echols and focused on medical records closer in time to the onset of symptoms. *Id.* at *24–25.

In addition, the Special Master determined Ms. Echols established *Althen* prong three, requiring a “proximate temporal relationship” between the vaccination and injury. *Id.* at *5, 23–24 (citing *Althen*, 418 F.3d at 1281). Here, the Special Master again relied on expert testimony and case studies. *Id.* at *23–24. Dr. DiCapua testified that Ms. Echols’s “rapid onset” was consistent with an immune response to the vaccine. *Id.* at *24 (citing Pet. Ex. 15 at 4). Dr. DiCapua highlighted a case report where a patient developed left arm weakness following the flu vaccine within twelve to sixteen hours as an example that such a proximate temporal relationship is plausible. (Pet. Ex. 15 at 4 (citing Taras et al., *Radial Nerve Motor Palsy Following Seasonal Influenza Vaccination (Case Report)*, 23 J. Surg. Orthop. Adv. 42 (2014))). Conversely, Dr. Tompkins testified that although it is “possible” a vaccine or “immunologic encounter” can generate a rapid reaction under fifteen hours, such a response “does not fit the facts seen here.” *Echols*, 2021 WL 4891589, at *23 (citing Resp’t Ex. F at 2–4, ECF No. 54-2). He also acknowledged that inflammation and a “less tight blood-nerve barrier” could allow a peripheral immune response. *Id.* at *24. Ultimately, the Special Master determined that Ms. Echols was entitled to compensation under the Vaccine Act. *Id.* at *26. The Secretary challenges these legal and factual conclusions.

II. Analysis

Under the Vaccine Act, the Court of Federal Claims reviews a decision of the Special Master upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2) (2018). The Court reviews such a decision to determine if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]” 42 U.S.C. § 300aa-12(e)(2)(B). Specifically, the Court applies the arbitrary and capricious standard to factual findings and reviews all legal conclusions *de novo*. *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). Importantly, “the standard of review for a mixed question [of law and fact] all depends—on whether answering it entails primarily legal or factual work.” *U.S. Bank Nat. Ass'n ex rel. CWC Capital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC*, 138 S. Ct. 960, 967 (2018) (involving determination by bankruptcy court).

This Court also applies the *Althen* prongs, listed above, to determine causation. Under *Althen* prong one, the petitioner must provide a “reputable medical theory” that the vaccine at issue can cause the type of injury alleged. *Althen*, 418 F.3d at 1278; *see also Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Although medical or scientific certainty is not required, a petitioner’s theory must still be “sound and reliable.” *Knudsen*, 35 F.3d at 548–49. Notably, “special masters may, but are not required to, analyze expert testimony” according to the more demanding *Daubert* standard. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citing *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1338–39 (Fed. Cir. 2010)). Under prong two, a petitioner must show, by preponderant evidence, “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. Finally, a petitioner must show “the alleged vaccine injury occurred within a medically-acceptable time-frame to satisfy *Althen* prong three.” *Contreras v. Sec'y of Health & Hum. Servs.*, 107 Fed. Cl. 280, 302 (2012); *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (“[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.”). These determinations are largely factual and specific from case-to-case.

Critically, the Court does not “reweigh the factual evidence,” or “assess whether the special master correctly evaluated the evidence.” *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871). Neither does the Court “examine the probative value of the evidence or the credibility of the witnesses.” *Id.* Instead, so long as the special master “considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision,” the Court upholds the Special Master’s determination. *Hines on behalf of Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (holding that “reversible error [is] extremely difficult to demonstrate”). The standard is “highly deferential.” *Cucuras v. Sec'y of Dep't of Health and Hum. Servs.*, 26 Cl. Ct. 537, 541 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993). The Court cannot “substitute its judgment for that of the special master merely because it might have reached a different conclusion.” *Snyder v. Sec'y of Dep't of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009).

Here, the Secretary raises two main objections to the Special Master’s decision. (Resp’t’s Mot. at 5). First, the Secretary objects to the Special Master’s evidentiary standard for proving causation under the *Althen* standard. The Secretary asserts the Special Master erred in concluding

that Ms. Echols satisfied *Althen* prong three and improperly lowered Ms. Echols's burden of proof under *Althen* prongs one and two. (*Id.* at 14, 18). Second, the Secretary argues the Special Master's factual conclusions that formed the basis of his decision were arbitrary and capricious. (*Id.* at 20). Specifically, the Secretary argues the Special Master disregarded relevant, contemporaneous medical records to find that Ms. Echols's symptoms occurred after her vaccination. (*Id.* at 20, 22). The Secretary requests that this Court reverse the Special Master's decision and dismiss Ms. Echols's petition. Each inquiry necessarily involves review of the Special Master's factual determinations; the Court addresses each in turn.

1. *The Special Master properly applied the evidentiary standard for proving causation.*

The Secretary argues that the Special Master misapplied all three *Althen* prongs to conclude that the administration of the flu vaccine caused Ms. Echols's neuralgic amyotrophy. (Resp't's Mot. at 14). First, the Secretary argues the Special Master erroneously found Ms. Echols satisfied prong three which requires petitioners to prove by a preponderance of evidence that there was a temporal relationship between the vaccination and injury. (*Id.* (internal citation omitted)). Second, the Secretary asserts the Special Master improperly lowered Ms. Echols's burden of proof under *Althen* prong one, requiring a medical theory linking the vaccination and injury, and prong two, requiring a showing that the injury was actually caused by the vaccination. (*Id.* at 18–20). Such arguments present mixed questions of law and fact.

When the Court reviews mixed questions of law and fact, it must determine whether answering it primarily involves legal or factual work. *See U.S. Bank Nat. Ass'n*, 138 S. Ct. at 967. Here, the Secretary first challenges the Special Master's determination that a temporal relationship existed between the administration of Ms. Echols's vaccine and the onset of symptoms. (Resp't's Mot. at 5, 14). Inherently, this involves reviewing the Special Master's factual findings that the onset of Ms. Echols's symptoms began three or four hours after vaccine administration. *Echols*, 2021 WL 4891589, at *13. Such a challenge is distinguishable from *Leming*, where the Court found that determining the meaning and scope of "surgical intervention" required it "to expound on the law, particularly by amplifying or elaborating on a broad legal standard" so it should be reviewed *de novo*. 154 Fed. Cl. 325, 333 n.6 (2021). Here, however, the Court is not asked to elaborate on *Althen* prong three, but to disrupt the Special Master's factual findings under the guise of reviewing a legal conclusion.

In reaching his legal conclusion that a temporal relationship existed between the vaccine and injury, the Special Master relied on expert testimony from Dr. DiCapua and scientific literature. *See Echols*, 2021 WL 4891589, at *5, 23–24. The Secretary argues that the rapid onset of Ms. Echols's symptoms—within three or four hours—is "unsupported by *any* literature or scientific evidence[.]" (Resp't's Mot. at 15) (emphasis added). Specifically, the Secretary discounts the significance of a case report relied on by the Special Master that involved a patient who developed symptoms twelve to sixteen hours after the flu vaccine. (*Id.* at 16). The Secretary questions the Special Master's reliance on that case report because the "time frame is at least three to four times longer than the one the Special Master found existed here." (*Id.*). The Secretary also argues its expert, Dr. Tompkins, convincingly opined that after the flu vaccine, "an immune response would be measured in days rather than hours." (*Id.*). "[C]ase reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their

evidentiary value’ . . . [but] ‘the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight.’ *See Paluck v. Sec’y of Health & Hum. Servs.*, 104 Fed. Cl. 457, 475 (2012) (quoting *Campbell v. Sec’y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2001), *aff’d*, 786 F.3d 1373 (Fed. Cir. 2015)).

If the Special Master’s conclusion was unsupported by *any* literature or scientific evidence, there is no doubt that the Secretary would be correct that such a conclusion would constitute reversible error. *See Althen*, 418 F. 3d at 1278. However, the Special Master’s finding in this case is not entirely detached from expert testimony or the scientific literature. *See Echols*, 2021 WL 4891589, at *5, 23–24. Instead, the Secretary challenges the weight that should have been given to a specific type of scientific evidence—namely, a case study—from which the Special Master drew his conclusion. (Resp’t’s Mot. at 16). However, the Court reviews the Special Master’s decision to ensure that factual evidence supports the conclusions, not to “reweigh” or “examine the probative value” of that evidence. *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *Moberly v. Sec’y of Dep’t of Health & Hum. Servs.*, 592 F.3d 1315, 1326 (Fed. Cir. 2010) (Special masters are “entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”).

Although the temporal relationship at issue here is shorter than the case study cited above, the Secretary fails to address the van Alfen study that found the onset of pain from neuralgic amyotrophy “generally becomes unbearable . . . within a few hours.” (Pet. Ex. 15-4 at 1). Similarly, van Alfen determined “the first signs of weakness appeared within [twenty-four] hours in 33.5% of the patients” which lends support to the Special Master’s conclusion. (Resp’t Ex. A-1 at 5). Here, the Special Master did not find that when Ms. Echols presented at the NEARC ED she had arm paralysis. *Echols*, 2021 WL 4891589, at *24. Rather, he determined the “progression” of symptoms occurred over several days. *Id.* Although the Secretary may disagree with that conclusion, such a conclusion is nonetheless plausible given the record before the Special Master. It matters not that another fact finder could reasonably conclude differently. *See Snyder*, 88 Fed. Cl. at 718.

Such determinations are distinguishable from cases like *Pafford*, where the Federal Circuit warned that “without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” 451 F.3d at 1355. Here, Ms. Echols provided, and the Special Master found plausible, scientific evidence from Dr. DiCapua and van Alfen that “the time between the vaccination and the onset of numbness and tingling was . . . more likely than not three to four hours.” *Echols*, 2021 WL 4891589, at *13. As a result, the Special Master found a temporal linkage between the flu vaccination and the onset of symptoms. *See id.* at *5, 23–24. Accordingly, a temporal relationship between Ms. Echols’s vaccination and injury falls within a “medically acceptable timeframe.” *Contreras*, 107 Fed. Cl. at 302.

Next, the Secretary argues the Special Master improperly lowered Ms. Echols’s burden of proof under *Althen* prongs one and two. (Resp’t’s Mot. at 18–20). The Secretary argues Ms. Echols failed to show that it was more likely than not that the flu vaccine caused her neuralgic amyotrophy. (*Id.* at 18). This also presents a mixed question of law and fact, requiring the Court to determine “whether answering it entails primarily legal or factual work.” *U.S. Bank Nat.*

Ass'n, 138 S. Ct. at 967. Again, the Secretary asks the Court to review the Special Master's credibility and factual determinations.

In challenging the Special Master's conclusion, the Secretary characterizes Dr. DiCapua's testimony that the symptoms can be caused by the flu vaccine as a "hypothes[is]."¹ (*Id.* (citing Dr. DiCapua's statement that "brachial neuritis can be caused by the flu vaccination and 'may involve both the innate and adaptive immune systems.'"). The Secretary argues such language is insufficient. (*Id.*). The Secretary contrasts Dr. DiCapua's testimony with Dr. Tompkins's who explained "medical literature suggesting an immune etiology . . . [is] primarily based upon associations in case reports [that] do not provide evidence of causation." (*Id.* at 18–19 (citing Resp't Ex. C at 2)). Similarly, the Secretary highlights that Dr. Callaghan testified there is "scant evidence" supporting causation. (*Id.* at 19 (citing Resp't Ex. A at 2)). But under the Vaccine Program, the task of assessing the exact probative weight of such competing evidence is assigned to the Special Master. *McCarren v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 142, 149 ("The court performs its analysis cognizant of the unique position and expertise of the special master under the Vaccine Act."). Here, the Special Master considered and evaluated all three experts' testimony as well as the literature and found Ms. Echols established *Althen* prongs one and two.

Preponderant evidence requires that the vaccination be "a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford*, 451 F.3d at 1355. However, "it need not be the sole factor or even the predominant factor." *Id.* at 1357 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). Critically, "close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280. Here, the Special Master was careful to find Ms. Echols's bursitis played a role in "loosen[ing] the blood nerve barrier," so her "brachial plexus [was] more vulnerable" when she received the flu vaccine. *Id.* at *26. Further, the Special Master determined that Ms. Echols's left shoulder pain prior to vaccine was "not so severe" that it was "improbable" she was experiencing weakness and numbness. *Id.* at *18. Such findings are in-line with *Kottenstette*, where the Federal Circuit upheld a special master's "search for medical probability rather than certainty[.]" 861 F.App'x. 433, 440 (Fed. Cir. 2021) (defining medical probability as "biologic credibility rather than specification of an exact biologic mechanism.").

The Special Master's conclusion follows the Federal Circuit's in *Capizzano* that "requiring either epidemiologic studies . . . or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect" is contrary to *Althen*. 440 F.3d at 1325. Here, the Special Master consistently reviewed the medical literature provided, including studies from van Alfen that were relied on by both parties, to determine causation-in-fact. Accordingly, the Special Master applied the correct standard of proof in determining *Althen* prongs one and two.

2. *The Special Master's factual findings were not arbitrary and capricious.*

The Secretary objects to the Special Master's analysis of medical records and factual determination that Ms. Echols's symptoms occurred after her vaccination. (Resp't's Mot. at 21). This is purely an issue of fact. First, the Secretary argues that the Special Master erroneously disregarded medical notes from the NEARC ED on November 12, that showed her left arm

weakness predated the vaccination. Those records specifically provided Ms. Echols's "chief complaint" was "left arm weakness since [November 6,]" and that those symptoms began "[four] day(s)" ago. (*Id.* at 20 (quoting Pet. Ex. 5 at 249)). The Secretary argues these detailed nursing notes should not be disregarded because contemporaneous medical records are "trustworthy" and should be given more weight than later, contradictory testimony. (*Id.* (citing *Cucuras*, 993 F.2d at 1528)). The Secretary further argues any internal inconsistency "actually bolsters [Ms. Echols's] report of her symptoms "because it indicates [she] likely stated more than once that her symptoms began prior to that very day." (*Id.* at 22). However, these arguments do not engage with this Court's standard of review.

To be upheld by this Court the Special Master need only consider relevant evidence, make plausible inferences, and articulate a rational basis for the decision. *See Hines*, 940 F.2d at 1528. Here, the Special Master did weigh the evidence from the NEARC ED. *Echols*, 2021 WL 4891589, at *13. Specifically, he found that the nursing notes highlighted by the Secretary contained two different dates as to the onset of Ms. Echols's symptoms and were contradicted by the records from her visit to the pulmonologist that morning and other NEARC ED notes. *Id.* at *8, 13 (second NEARC ED notes dating onset of symptoms to November 12). At her pulmonologist appointment, Ms. Echols "denie[d] tingling or numbness [or] muscular weakness[] and even more importantly, her provider found "no muscle weakness, no sensory loss." *Id.* at *8. This is distinguishable from cases where a petitioner fails to report all their symptoms to their provider. *See Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (noting "[a]lthough these medical records are silent about the existence of any lingering symptoms, they are also silent about the nonexistence of such symptoms."). Here, Ms. Echols's provider noted a nonexistence of left arm symptoms. Therefore, the Special Master attached greater weight to the pulmonology and second NEAR ED notes, rather than wholly disregarding contemporaneous medical records.

Second, the Secretary argues the Special Master arbitrarily and capriciously disregarded medical records from Ms. Echols's orthopedist regarding the onset of her left arm symptoms. (Resp't's Mot. at 22). The Secretary emphasizes the specificity of the record indicating Ms. Echols "woke up last Thursday [November 12] morning with numbness and unable to use her left arm. She went to the emergency room where they did a CT scan of the head and neck and told her that it did not appear that she had a stroke . . ." (*Id.* (quoting Pet. Ex. 11 at 9)). The Secretary argues that such specificity credibly establishes that Ms. Echols's symptoms began before her vaccination at the pulmonologist at 11:33 AM. (*Id.* at 22.). The Secretary further argues that the Special Master's finding that Ms. Echols's orthopedist "must have been mistaken" regarding the onset of symptoms is "inexplicabl[e]." (*Id.* at 23).

In making his factual findings, the Special Master reviewed a multitude of medical records that contained contradictory information when concluding that Ms. Echols's symptoms began after her flu vaccination on November 12. Weighing the factual evidence and examining its probative value is within the purview of the special master. *Porter*, 663 F.3d at 1249. Here, the Special Master reviewed Ms. Echols's orthopedist's records and determined they had less value than a series of other medical records that provided a consistent timeline regarding her left arm paralysis and pain. *Echols*, 2021 WL 4891589, at *16. For example, Ms. Echols's neurologist noted that her arm paralysis "has lasted for [seven] day(s)," dating the symptoms to November 12. (Pet. Ex. 2 at 12). The Secretary argues this is not specific to the relevant

symptoms of weakness, numbness, and tingling and does not indicate whether they began before or after Ms. Echols's vaccination. (Resp't's Mot. at 23). However, this is unavailing. When the finding of fact is "based on evidence in the record that [is] not wholly implausible, [this Court is] compelled to uphold the finding as not being arbitrary or capricious." *Porter*, 663 F.3d at 1249 (internal citation omitted). The Special Master plausibly found that Ms. Echols's symptoms were relevant and began on November 12, the date of her vaccination. Accordingly, the Court upholds the factual findings as not arbitrary or capricious.

Based on the foregoing, the Court finds that the Special Master considered the relevant evidence of record, drew plausible inferences, and articulated a rational basis for the decision. The Special Master's September 14, 2021 ruling was not arbitrary, capricious, an abuse of discretion, or contrary to law.

III. Conclusion

For the stated reasons, the Court hereby **DENIES** the Secretary's Motion for Review, (ECF No. 91), and **AFFIRMS** the Special Master's September 14, 2021 decision. The Clerk is directed to enter judgment accordingly.

The Court has filed this ruling under seal. The parties shall confer to determine proposed redactions to which all the parties agree. Per Vaccine Rule 18(b), no later than December 14, 2022, the parties shall file a joint status report indicating their agreement with the proposed redactions, attaching a copy of those pages of the Court's ruling containing proposed redactions, with all proposed redactions clearly indicated.

IT IS SO ORDERED.



s/ David A. Tapp
DAVID A. TAPP, Judge